REMARKS/ARGUMENTS

Claims 16 to 33 have been undergoing examination with claims 1 to 15 and 34 to 36 standing withdrawn. Claims 16 and 25 are amended. Claims 23 and 24 are canceled without prejudice. After entry of these amendments, claims 16 to 22 and 25 to 33 will be undergoing examination

Support for the amendments to the claims.

Claim 16 was amended to set forth a CB1 receptor antagonist.. Support for this subject matter is found in the first sentence of paragraph 28.

The amended recitals of claim 25 find support in the specification at page 69, in the first sentence of paragraph 247.

Accordingly, the Applicants believe the amendments to the claims add no new matter and respectfully request their entry.

Response to the rejection of claims 23-25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Without acquiescing on the merits, the Applicants have canceled claims 23 and 24 to expedite prosecution of the application. Claim 25 has been amended to set forth the biological samples and the assay conditions used to determine the IC_{50}'s set forth in the claims. Accordingly, the Applicants believe the IC_{50}'s values are not indefinite and respectfully request reconsideration and withdrawal of this grounds of rejection.

Response to the rejection of claims 18-19, 23-25 and 33 are rejected under 35 U.S.C. 112, second paragraph, as lacking antecedent basis.

Applicants have amended claim 16 to provide the missing antecedent basis. The Applicants thank the Examiner for catching the error. Accordingly, the Applicants respectfully request reconsideration and withdrawal of this grounds of rejection.

Response to the rejection of claims 16-22, 26-31 and 33 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by WO 99/60987.

A. Standard for anticipation

For a rejection of claims under § 102 to be properly founded, the Examiner must establish that a single prior art reference either expressly or inherently discloses each and every element of the claimed invention. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Verdegaal Bros. V. Union Oil Co. Of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

In *Scripps Clinic & Research Found. v. Genentech, Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1991), the Federal Circuit held that:

> Invalidity for anticipation requires that all of the elements and limitations of the claim are found with a single prior art reference. . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Id.* at 1010.

Anticipation can be found, therefore, only when a cited reference discloses all of the elements, features, or limitations of the presently claimed invention.

B. The Action's analysis and the scope of the claims as amended.

The Action is predicated on the Examiner's position:

> The '987 reference teaches a composition in dosage unit form. (see page 10 line 6) comprising OEA and SR141716A (see page 6 lines 6-1 0) wherein the Examiner interprets the word "composition" to include actives that are mixed or not mixed'together and is not limited to components which are physically connected.

The above interpretation of scope of the claimed compositions is at odds with the claim recital. The base claim recites:

> A pharmaceutical composition for reducing food consumption in a mammal, said composition *comprising* a PPARα agonist and a cannabinoid CB1 receptor antagonist. [italics added for emphasis]

The Action posits that the term "composition" does not require that the described components be physically connected. This position is incorrect. The Applicants include with Exhibit A, page

185 from "The Cambridge Dictionary of Science and Technology, which defines "composition" thusly:

> Composition (chem.). The nature of the elements *present* in a substance and the proportion in which they occur.

[italics added for emphasis]. Accordingly, the Applicants submit that the PPARα agonist and cannabinoid CB1 receptor antagonist of the claims must be physically present together in the composition.

Moreover, even assuming for the sake of argument that the Action's wholly unreasonable interpretation of the term "composition' were correct, the term *comprising* would further limit the composition subject matter of the claim and is a well known term of art. See, MPEP§2111.03 at page 2100-44, left column at page, which sets forth that

> "Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim. [quoting *Genentech, Inc. v. Chiron Corp.*, 112F3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997)]

Accordingly, the claimed composition must contain both the PPARα agonist and a cannabinoid CB1 receptor antagonist.

C. Traversal of the rejection.

The Action points to the specification as allegedly disclosing "compositions" of both OEA and SR141716A at page 6, lines 6 to 10 of WO 99160987. This allegation is simply incorrect. The cited passages relate to Figure 2 of the reference. Figure 2 shows only that the effects of PEA were blocked by prior administration of Rimonabant (See, the figure itself and the discussion of the figure at Example 2 on page 13 and 14 of the reference). OEA lacked discernible activity in this test system and so there was *no* described testing of OEA in Rimonabant treated animals. Absent any effects of OEA, there was *no* reason to see if any effects were mediated by the CB1 receptor. Accordingly, there was no use of Rimonabant or OEA in the same rat. AND certainly, given the lack of an OEA effect, no composition comprising both OEA and rimonabant is even suggested by the reference.

Turning to PEA and anandamide, the active agents set forth in the specification of WO 99/60987 for use in treating pain, these two active agents are CB1 receptor agonists.

Rimonabant is an CB1 receptor *antagonist* which would accordingly oppose the desired anti-pain effect of these two active principles. Accordingly, nothing in WO 99/60987 suggests a pharmaceutical composition which would include either PEA or anandamide along with rimonabant. In fact, rather than disclose the claimed subject matter, the reference teaches away from such pharmaceutical compositions as one component of the proffered combination would, according to the cited reference, undo the desired effect of the other component.

As the WO 99/60987 reference can not be fairly described as disclosing or suggesting the claimed subject matter and fails to provide all the elements of the rejected claims, the Applicants respectfully request that this grounds of rejection be reconsidered and withdrawn.

Response to the provisional rejection of claims 16-31 and 33 as on the ground of nonstatutory double patenting over claims 59 and 61 -62 of copending Application No. 11/587100.

Claims 59 and 61 to 61 of co-pending Application No. 11/587100 are drawn to compositions of a PPARα agonist other than PEA and a second agent which is a CB1 receptor *agonist*. The pending claims of the present application set forth a CB1 receptor *antagonist*. The subject matter of the cited claims from the 11/587100 application and the present application therefore are patentably distinct.

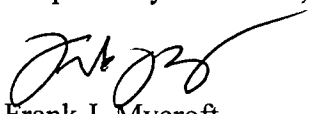
Accordingly, the Applicants respectfully request that this grounds of rejection be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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